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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,912	09/11/2000	Charles A. Vacanti	07917-082002	2934

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	12

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,912	VACANTI ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 16 June 2003 (Paper No. 11) has been received and entered in full. Claims 1-53 have been cancelled and claims 54-61 have been added.

Withdrawn Rejections And/Or Objections

2. The objection to the Oath/Declaration as set forth at pp. 2 ¶4 in the previous Office Action (Paper No. 9, 12 December 2002) is *withdrawn* in view of Applicant's arguments (Paper No. 11, 16 June 2003).

3. The objection to the Title as set forth at pp. 3 ¶6-7 in the previous Office Action (Paper No. 9, 12 December 2002) is *withdrawn* in view of Applicant's amendments (Paper No. 11, 16 June 2003).

4. The objection to the Specification as set forth at pp. 3 ¶10 in the previous Office Action (Paper No. 9, 12 December 2002) is *withdrawn* in view of Applicant's amendments (Paper No. 11, 16 June 2003).

5. The rejection of claims 41-44 under 35 U.S.C. §112 ¶1 as set forth at pp. 3-7 ¶11-18 in the previous Office Action (Paper No. 9, 12 December 2002) is *moot* in view of Applicant's cancellation of said claims (Paper No. 11, 16 June 2003).

6. The rejection of claims 41-44 under 35 U.S.C. §102(b) as set forth at pp. 7-9 ¶19-22 in the previous Office Action (Paper No. 9, 12 December 2002) is *moot* in view of Applicant's cancellation of said claims (Paper No. 11, 16 June 2003).

7. The rejection of claims 41 and 43 under 35 U.S.C. §102(e) as set forth at pp. 7-9 ¶23-24 in the previous Office Action (Paper No. 9, 12 December 2002) is *moot* in view of Applicant's cancellation of said claims (Paper No. 11, 16 June 2003).

Maintained Rejections And/Or Objections

8. The denial of priority of the instant application to Application No. 09/066038 (now US Patent No. 6,027,744) as set forth at pp. 2 ¶2 in the previous Office Action (Paper No. 9, 12 December 2002) was not challenged in Applicant's response (Paper No. 11, 16 June 2003). Therefore the instant application is granted the priority date of Application No. 09/200,033 (now US Patent No. 6,171,610) which is 25 November 1998.

9. The grounds for the objection to the drawings as set forth at pp. 3 ¶8-9 in the previous Office Action (Paper No. 9, 12 December 2002) is *corrected* in view of Applicant's arguments (Paper No. 11, 16 June 2003). The Examiner notes that the grounds for the objection were incorrect, the corrected grounds for objection are set forth below.

10. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "10, 12, 14, 16, and 18". A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims **54-61** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of isolating a stem cell from a tissue selected from the group consisting of heart, bladder, intestine, lung, liver, kidney, pancreas, or adrenal medulla, the method comprising: providing said tissue; dissociating said tissue and exposing the dissociated tissue to trypsin; and triturating the degraded tissue such that differentiated cells are destroyed, and culturing said stem cells in the presence of a cytokine is selected from the group consisting of bFGF, NGF, and EGF* does not reasonably provide enablement for *a method of isolating a neural stem cell from any innervated tissue, a method wherein neuroendocrine stem cells are isolated from any innervated tissue, or cultured in the presence of any other cytokines, or any other isolated neural stem cells*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

12. The claims are drawn quite broadly to a method of isolating a neural stem cell from any innervated tissue in mammal. The language of said claims encompasses all tissue in a mammal as the nervous system innervates ALL tissues. It is known that only certain areas of the

mammalian organism contain neural stem cells, especially neuroendocrine neural stem cells, such as the pancreas {Bouwens and Blay (September 1996) "Islet Morphogenesis and Stem Cell Markers in Rat Pancreas." The Journal of Histochemistry and Cytochemistry **44**(9): 947-951}.

13. The above invention is drawn to a method of isolating a neural stem cell from any innervated tissue in mammal. The specification teaches that stem cells can be isolated from heart, bladder, intestine, lung, liver, and kidney tissue.

14. The specification fails to provide any guidance for the successful isolation of a neural stem cell from all innervated tissues, especially neuroendocrine stem cells, and since resolution of the various complications in regards to neural stem cells, especially in adult mammalians, is highly unpredictable, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed to the full scope would require the *de novo* determination of formulations with known neural stem cell markers, proteins, genes, and locations and then practice of the method, then confirmation of the phenotype. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed. Additionally, a person skilled in the art would recognize that predicting the efficacy of practicing the method based solely on its performance in a limited number of tissues as highly problematic. Thus, although the specification prophetically considers and discloses general methodologies of using the claimed methods in a broad range of tissues, such a disclosure would not be considered enabling

since the state of neural stem cells is highly unpredictable. The factors listed below have been considered in the analysis of enablement:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

15. The following references are cited herein to illustrate the state of the art of stem cells.

16. Concerning the breadth of the claims, Ahmed *et al.* (August 1995) "BDNF Enhances the Differentiation but Not the Survival of CNS Stem Cell-Derived Neuronal Properties." The Journal of Neuroscience **15**(8): 5765-5778 teaches that the effectiveness of BDNF treatment of neural stem cells decreases over time (Figure 6). Thus the skilled artisan is not assured that any given cytokine or growth factor will maintained the desired effect on the neural stem cell cultures isolated by the claimed method.

17. On the nature of the invention, Santa-Olalla and Covarrubias (1 October 1995) "Epidermal Growth Factor (EGF), Transforming Growth Factor-α (TGF-α), and Basic Fibroblast Growth Factor (bFGF) Differentially Influence Neural Precursor Cells of Mouse Embryonic Mesencephalon." Journal of Neuroscience Research **4**(2): 172-183 teach that EGF, TGF-α, and bFGF all differ in their effects on neural stem cell cultures (Figures 2 and 3; Table 1 and 2). Thus the skilled artisan is confronted with an undue burden of experimentation to test and verify that each individual cytokine and/or growth factor has the desired effect on the neural stem cell cultures isolated by the claimed method.

18. In light of the prior art, Murphy *et al.* (August 1997) "Neural Stem Cells." Journal of Investigative Dermatology Symposium Proceedings **2**(1): 8-13 teach that neurotrophic (growth factors and cytokines) as well as the initial location with the developing neural tube as well as their final location post-migration from the proliferative zone of the neural tube determine the cellular fate of a neural stem cell (Abstract; Figure 1; pp. 11). Thus the prior art teaches that all of these factors must be taken into consideration to practice the invention was claimed. Therefore an undue burden of experimentation is imposed upon the skilled artisan to practice the full scope of the instant claims.

19. Concerning the predictability of neural stem cell isolation and maintenance, Mehler *et al.* (June/July 1995) "Cytokines Regulate the Cellular Phenotype of Developing Neural Lineage Species." Int. J. Devl. Neuroscience **13**(3/4): 213-240 teach that a single neural stem cell can give rise to a number of different cell types dependent upon the growth factor or cytokine, concentration, and time of incubation (Table 1; pp. 233). Thus the skilled artisan must resort to trial and error to determine which cytokines, what concentration, and what time of incubation is necessary to give rise to any given differentiated cell type.

20. Thus the specification of the instant application fails to provide adequate guidance for one of skill in the art to overcome the unpredictability and challenges neural stem cell isolation as exemplified in the references herein.

21. Claims **54-61** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) the length of time in which the neural stem cell is cultured,

2) the age of the mammal (adult, juvenile, embryonic) since it will depend greatly upon whether organogenesis has occurred, and 3) the percentage of trypsin used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims **54, 55, 56, 57, 60,** and **61** are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/15226 (23 May 1996) Weiss and Reynolds. WO 96/15226 teaches a method of isolating neural stem cells comprising dissecting spinal cord tissue from mice, placing the extracted tissue in artificial cerebrospinal fluid (aCSF), chopping the tissue into fine pieces, treating said tissue with trypsin, triturating said tissue, and then centrifuging said tissue preparation to separate the neural stem cells thus meeting the limitations of claims 54, 55, 57, and 61 (Example 4). WO 96/15226 also teaches that neural stem cells can be isolated from mammals including but not limited to humans and mice, thus meeting the limitations of claims 54, 60, and 61 (Example 5). WO 96/15226 further teaches that neural stem cells can be isolated from non-nervous tissue such as liver and intestine thus meeting the limitations of claim 56 (pp. 3 lines 16-21).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims **54, 55, 56, 57, 59, 60,** and **61** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/15226 (23 May 1996) Weiss and Reynolds and Cornelius *et al.* (1997) "*In Vitro*-Generation of Islets in Long-Term Cultures of Pluripotent Stem Cells from Adult Mouse Pancreas." Horm. Metab. Res. **29**: 271-277.

24. WO 96/15226 teaches a method of isolating neural stem cells comprising dissecting spinal cord tissue from mice, placing the extracted tissue in artificial cerebrospinal fluid (aCSF), chopping the tissue into fine pieces, treating said tissue with trypsin, triturating said tissue, and then centrifuging said tissue preparation to separate the neural stem cells thus meeting the limitations of claims 54, 55, 57, and 61 (Example 4). WO 96/15226 also teaches that neural stem cells can be isolated from mammals including but not limited to humans and mice, thus meeting the limitations of claims 54, 60, and 61 (Example 5). WO 96/15226 further teaches that neural stem cells can be isolated from non-nervous tissue such as liver and intestine thus meeting the limitations of claim 56 (pp. 3 lines 16-21). However WO 96/15226 does not teach the isolation of neural stem cells from the mammalian pancreas.

25. Cornelius *et al.* teaches the isolation of neuroendocrine neural stem cells from the pancreata from adult mice (pp. 272).

26. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as taught by WO 96/15226 to isolate neural stem cells from the pancreata of mice in light of the teachings of Cornelius *et al.*

27. A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because sufficient guidance was given by WO 96/15226 to isolate stem cells. The teachings of Cornelius *et al.* provided an additional source of neural stem cells.

28. A person of ordinary skill in the art at the time of the invention would be motivated to isolate neural stem cells from pancreata of mice because of their usefulness in research and therapy as taught by Cornelius *et al.* (pp. 276).

29. Thus the invention as a whole was *prima facia* obvious over the prior art.

30. Claims **54, 55, 56, 57, 60,** and **61** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/15226 (23 May 1996) Weiss and Reynolds and Warejcka *et al.* (May 1996) "A Population of Cells Isolated from Rat Heart Capable of Differentiating into Several Mesodermal Phenotypes." Journal of Surgical Research **62**(2): 233-242.

31. WO 96/15226 teaches a method of isolating neural stem cells comprising dissecting spinal cord tissue from mice, placing the extracted tissue in artificial cerebrospinal fluid (aCSF), chopping the tissue into fine pieces, treating said tissue with trypsin, triturating said tissue, and then centrifuging said tissue preparation to separate the neural stem cells thus meeting the limitations of claims 54, 55, 57, and 61 (Example 4). WO 96/15226 also teaches that neural stem

cells can be isolated from mammals including but not limited to humans and mice, thus meeting the limitations of claims 54, 60, and 61 (Example 5). WO 96/15226 further teaches that neural stem cells can be isolated from non-nervous tissue such as liver and intestine thus meeting the limitations of claim 56 (pp. 3 lines 16-21). However WO 96/15226 does not teach the isolation of stem cells from a mammalian heart.

32. Warejcka *et al.* teaches the isolation of stem cells from rat heart (pp. 234).

33. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as taught by WO 96/15226 to isolate stem cells from rat heart in light of the teachings of Warejcka *et al.*

34. A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because sufficient guidance was given by WO 96/15226 to isolate stem cells. The teachings of Warejcka *et al.* provided an additional source.

35. A person of ordinary skill in the art at the time of the invention would be motivated to isolate stem cells from rat heart because of their usefulness in research and therapy as taught by Warejcka *et al.* (pp. 241).

36. Thus the invention as a whole was *prima facia* obvious over the prior art.

37. Claims **54, 55, 56, 57, 60,** and **61** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/15226 (23 May 1996) Weiss and Reynolds and Emura (January 1997) "Stem Cells of the Respiratory Epithelium and their In Vitro Cultivation." *In Vitro* Cell. Dev. Biol. **33**: 3-14.

38. WO 96/15226 teaches a method of isolating neural stem cells comprising dissecting spinal cord tissue from mice, placing the extracted tissue in artificial cerebrospinal fluid (aCSF),

chopping the tissue into fine pieces, treating said tissue with trypsin, triturating said tissue, and then centrifuging said tissue preparation to separate the neural stem cells thus meeting the limitations of claims 54, 55, 57, and 61 (Example 4). WO 96/15226 also teaches that neural stem cells can be isolated from mammals including but not limited to humans and mice, thus meeting the limitations of claims 54, 60, and 61 (Example 5). WO 96/15226 further teaches that neural stem cells can be isolated from non-nervous tissue such as liver and intestine thus meeting the limitations of claim 56 (pp. 3 lines 16-21). However WO 96/15226 does not teach the isolation of lung stem cells.

39. Emura teaches that stem cells can be found in solid organs like the liver, intestine, and lung (Abstract; pp. 4; Table 1 and 2).

40. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as taught by WO 96/15226 to isolate stem cells from mammalian lung in light of the teachings of Emura.

41. A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because sufficient guidance was given by WO 96/15226 to isolate stem cells. The teachings of Emura provided an additional source.

42. A person of ordinary skill in the art at the time of the invention would be motivated to isolate neural stem cells from lungs because of their usefulness in research and therapy as taught by Emura (pp. 3).

43. Thus the invention as a whole was *prima facia* obvious over the prior art.

44. Claims **54, 55, 56, 57, 60,** and **61** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/15226 (23 May 1996) Weiss and Reynolds and Seidl & Unsicker (1989) "Survival and neuritic growth of sympathoadrenal (chromaffin) precursor cells in vitro." Int J Dev Neurosci. **7**(5):465-73.

45. WO 96/15226 teaches a method of isolating neural stem cells comprising dissecting spinal cord tissue from mice, placing the extracted tissue in artificial cerebrospinal fluid (aCSF), chopping the tissue into fine pieces, treating said tissue with trypsin, triturating said tissue, and then centrifuging said tissue preparation to separate the neural stem cells thus meeting the limitations of claims 54, 55, 57, and 61 (Example 4). WO 96/15226 also teaches that neural stem cells can be isolated from mammals including but not limited to humans and mice, thus meeting the limitations of claims 54, 60, and 61 (Example 5). WO 96/15226 further teaches that neural stem cells can be isolated from non-nervous tissue such as liver and intestine thus meeting the limitations of claim 56 (pp. 3 lines 16-21). However WO 96/15226 does not teach the isolation of stem cells from the rat adrenal medulla.

46. Seidl & Unsicker teach the isolation, purification, and culture of sympathoadrenal precursors from rat adrenal glands (pp. 465; Figure 5).

47. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as taught by WO 96/15226 to isolate neural stem cells from rat adrenal medulla in light of the teachings of Seidl & Unsicker.

48. A person of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because sufficient guidance was given by WO 96/15226 to isolate stem cells. The teachings of Seidl & Unsicker provided an additional source.

49. A person of ordinary skill in the art at the time of the invention would be motivated to isolate neural stem cells from rat adrenal medulla because of their usefulness in research and therapy as taught by Seidl & Unsicker (pp. 471-472).

50. Thus the invention as a whole was *prima facia* obvious over the prior art.

Summary

51. Claims 54-61 are hereby rejected.

52. The following patents, published patent applications, and articles were found by the Examiner during the prior art search and are here made of note:

a. US 5589376 (31 December 1996) Anderson *et al.*

b. US 5824489 (20 October 1998) Anderson *et al.*

c. US 5753506 (19 May 1998) Johe

d. Dabeva *et al.* (July 1997) "Differentiation of pancreatic epithelial progenitor cells into hepatocytes following transplantation into rat liver." PNAS **94**: 7356-7361.

e. Roskams *et al.* (April 1996) "'Undifferentiated progenitor cells' in focal nodular hyperplasia of the liver." Histopathology **28**(4): 291-299.

f. Notter *et al.* (1986) "Neuronal properties of monkey adrenal medulla in vitro." Cell Tissue Research **244**: 69-76.

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 11, 2003